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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,490	03/30/2006	Tatsuo Tsutsui	P28491	5410

7055 7590 02/07/2007  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER
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THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/07/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/07/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

## Office Action Summary

Application No.

10/550,490

Applicant(s)

TASUO TSUTSUI

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 6 is/are rejected.
- 7) ☒ Claim(s) 2 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/30/06 &amp; 01/24/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 03/20/06 & 01/24/07 were filed before the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4,6 are rejected under 35 U.S.C. 102(b) as being anticipated by Oki et al. ( JP 09-276405).

Oki et al. disclose a powder delivery device having a capsule housing , a capsule K, blades 20 or 49 which cuts/pierces the capsule K at a lateral direction with respect to the axial length of the capsule, a pump 8 which is pressurized ( see figure 6) and powder medicament in the capsule is released via the passages in the branched top ends wherein the ends are tubular. and for insertion into the nasal cavity. Further, Oki et

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al. disclose a pump 8 and a one way valve 12 and an air intake valve 17 at the bottom of the pump 8. See figures 1-11.

Claims 1,3 are rejected under 35 U.S.C. 102(e) as being anticipated by Kladders et al. ( US 2004/0173211 A1).

Kladders et al. disclose a device comprising a capsule 1 with a medicine delivery part with one end in the capsule housing/holding part ,a pump considered to be 5 ( in as much as applicant has shown and disclosed a pump so has Kladders et al.), a capsule setting/detaching part 19 having cutting blades 20 for piercing the capsule at both axial ends of the capsule 1. See figures 1-4. Kladders et al. specifically discloses a Bernoulli inhaler for delivery of powder inhaler. The tube is given the broadest interpretation by the Examiner.

Claims 1,3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kladders ( US 4,889,114).

Kladders is rejected similar to Kladders et al. above. See figure 4.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kladder ( US 4,889,114) in view of Ohki et al. (US 5,810,004).

Kladder discloses the invention as substantially claimed. Kladders disclose a powdered pharmaceutical delivery device comprising a single delivery at the top end , having a capsule which is pierced by cutting blades 11 at a lateral direction to the elongated axis of the capsule 15. However, Kladder is silent to a pump and a branched top end. Ohki discloses a powdered delivery device having a capsule K, a pump 15, a medical delivery part having one or branched top end 18,19 and a cutting blade 6 which cuts the capsule. It would have been obvious to one of ordinary skill in the art of powder medicament delivery to have modified the powder delivery device of Kladders et al. with a pump and branched delivery end as taught by Ohki et al. in order to provide an increased velocity of delivery of the medicated powder to the region of the body which could bypass areas of the body without being biologically or chemically broken down before reaching the target region. With respect to the branched delivery end, Ohki teaches delivery of inhaled powder medicaments by nose or mouth, it would have been obvious to modify the delivery end of Kladders to a branched end as taught by Ohki et al. in order to delivery of powder agents through the nasal passage.

#### ***Allowable Subject Matter***

Claims 2 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763